Remarks

Claims 1, 3, 5, 7-12, 25-29 are pending in the application after entry of the herein amendment. Claims 26-29 stand withdrawn pursuant to a restriction requirement. Claims 6 and 37, withdrawn from consideration as being directed to non-elected species, have been cancelled. Claim 36 has been cancelled.

Claims 1 and 26 have been amended to recite that the bioadhesive pharmaceutical formulation is in the form of a buccal melt product. Support for the amendment is found in claim 4, which has been canceled.

Reconsideration of all grounds of rejection is requested in view of the above changes, and the following remarks.

All claims amendments and claim cancellations are made without prejudice to the filing of one or more continuing applications.

Response to Objection to Claim 36

The cancellation of claim 36 overcome the objection.

Response to 35 USC 103 Rejections

Ammeraal *et al.*

Claims 1, 3, 5, 7 and 25 have been rejected under 35 USC § 103 (a) as being unpatentable over Ameraal *et al.*

Claim 1 has been amended to recite that the bioadhesive pharmaceutical formulation is in the form of a buccal melt product. The Examiner does not point to any teaching of any β-limit dextrin product described in Ameraal *et al.* as being in the form of a buccal melt. Indeed, Examiner correctly points out that Ameraal *et al.* fails to expressly state that the products described therein are in the form of buccal melts. Notwithstanding this clear absence of a teaching of a buccal melt, Examiner alleges that this feature would have been an "obvious design choice".

A buccal melt product must have certain properties to function, namely:

(i) capacity to form a matrix which when hydrated can release ***rapidly*** the active;

(ii) be able to form a solid dosage format with enough strength for transportation;

(iii) capacity to bind and release the active agent in/from the matrix;

(iv) be preferably mucoadhesive (bioadhesive) and thus stick to the mucosal membrane of the oral cavity;

v) provide a good sensory sensation in the mouth;

(vi) be stable; and

(vii) be able to carry a range of actives, pharmaceuticals, flavors etc.

It is evident that Ammeraal *et al.* does not teach these properties for any formulation. Indeed Examiner points out at column 1, lines 63-67 that the ß-limit dextrins "are useable for *slow-release* of different compounds such as sweeteners and drugs" (emphasis added). This would be a distinct disadvantage for a buccal melt product which requires rapid or "flash melt" release of the active agent in the oral cavity. In contrast to the opinion of the Examiner on page 6, second paragraph of the office action, Ammeraal *et al.* teaches away from the use of freeze dried ß-limit dextrins in a buccal melt product, since a slow release product as described by Ammeraal *et al.* would not have the most important property of all necessary for a buccal melt, that of rapid release of the active agent.

Moreover Ammeraal *et al.* provides no teaching how a buccal melt product would be manufactured comprising a freeze dried ß-limit dextrin and an active agent. The reference to freeze drying at column 1, line 60 is a reference to the recovery of ß-limit dextrins from extracted plant material, and not to the formation of a buccal melt product as suggested by Examiner. The exemplification of Ammeraal *et al.* is completely directed to processing ß-limit dextrins for food and beverage applications, and not to the manufacture of a buccal melt product as disclosed in the present application.

Accordingly, the subject matter of amended claim 1 would not have been obvious to one of ordinary skill in the art over Ammeraal *et al.* Claim 1 is allowable.

Claims 3, 5, 7 and 25 depend directly or indirectly from claim 1, and recite further features of the bioadhesive pharmaceutical formulation of claim 1. Accordingly these claims are

likewise allowable over Ammeraal *et al.*

Kono *et al.*

Claims 1, 8-12 and 36 have been rejected under 35 USC § 103 (a) as being unpatentable over Kono *et al.* Claim 36 has been cancelled.

Claim 4 is noted to be free of the rejection over Kono *et al.* As claim 1 has been amended to incorporate the feature of claim 4, it is also free of the rejection Kono *et al.* Claims 8-12, which depend directly from claim 1, are likewise allowable.

Request for Rejoinder of Claims

Claim 26, currently withdrawn and amended, is directed to a method of delivering an active agent, by administering a formulation having the elements of the formulation of amended claim 1. In view of the allowability of claim 1, withdrawn claim 26, as well as its dependent claims 27-29, are now rejoinable pursuant to MPEP 801.04. Rejoinder is requested.

Conclusion

The claims remaining in the application are in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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